

Applicants : Vadiraja Murthy and Edward R. Burns
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Olsson detected elevated levels of hemoglobin and adenylate kinase in various samples subjected to different periods of storage. Specifically, Olsson found some correlation between the amount of accumulated hemoglobin and adenylate kinase in samples of whole blood and red blood cell concentrates following storage (see Figure 6 of Olsson). Olsson also measured an increase in the accumulation of extracellular adenylate kinase during storage of platelets (see Figure 7 of Olsson). Although Olsson found some correlation between hemoglobin and adenylate kinase, the ratio of hemoglobin to extracellular adenylate kinase between red blood cell concentrates depicted in Figures 6A and 6B was significantly different (see pages 442 and 445 of Olsson).

In addition, although Olsson suggested that measuring the level of adenylate kinase may be useful for studying the lytic processes of platelets, and possibly the testing of blood cell packs prior to transfusion, there is absolutely no teaching or suggestion in Olsson to use erythrocyte adenylate kinase activity for diagnosing erythrocyte hemolysis that takes place *in vivo*. In this regard, Olsson provides no experimental evidence to support that erythrocyte adenylate kinase activity actually correlates with hemolysis *in vivo*. In addition, even assuming there is a correlation *in vivo*, Olsson provide no teaching or suggestion that the erythrocyte adenylate kinase released in the patient's blood is stable and is not taken up by any tissues or cells or is in any way extruded from the patient's body that would make such a correlation meaningful and detectable.

not claimed
NO X
sys

Finally, Olsen provides no teaching or suggestion that the presence of at least about 20 U/L erythrocyte adenylate kinase activity is indicative of erythrocyte hemolysis in the subject, as required by Claim 20.

hemolysis in vivo vs invitro
method is same

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For these reasons, applicants submit that the claimed invention is patentable over Olsson. Accordingly, reconsideration and withdrawal of this rejection, and allowance of Claim 20, are respectfully requested.

No fee is deemed necessary in connection with the filing of this Communication. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully Submitted,

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